

REMARKS

The outstanding Office Action addresses and rejects claims 6-12. Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Claim 7 has been amended to clarify the claim language. In particular, to clarify that the ultrafiltration membrane has a skin-to-skin crush seal and that this seal allows the ultrafiltration membrane to be active over the full wetted area of the vessel wall. As stated originally, the claim language may not have been entirely clear as to how the skin-to-skin seal was related to the ultrafiltration membrane and the vessel wall. In addition, a possible problem with proper antecedent basis for "said filter" has been eliminated. Claim 8 has been amended so as to be consistent with the amended claim language of claim 7. Claim 12 has been amended as suggested by the Examiner to correct a typographical error.

Support for these amendments can be found throughout the specification and drawings, for example at page 6, last paragraph. No new matter has been added.

35 U.S.C. § 102(e) Claim Rejections

The Examiner rejects claims 7 and 9-12 pursuant to 35 U.S.C. § 102(e), alleging that the claims are anticipated by U.S. Patent 6,269,957 to Bowers et al. ("Bowers"). In particular, the Examiner argues that Bowers discloses an ultrafiltration vessel comprising a vessel having an interior wall with an outlet port, an ultrafiltration membrane covering the port, and the membrane having a skin-to-skin seal effective to cover a full area of the vessel wall.

Applicants traverse this rejection and submit that the pending claims distinguish over the Bowers reference.

The claimed invention is directed to an ultrafiltration vessel with an ultrafiltration membrane covering the outlet port. The membrane includes a skin-to-skin crush seal that allows the ultrafiltration membrane to cover a full area of the vessel wall. Applicants have found that using a skin-to-skin crush seal provides several advantages over the prior art, including permitting 100% of the wetted area of the vessel interior to be formed from active membrane.

The resulting filter can achieve maximum filtration, leading to maximum concentration rate and protein recovery. In addition, nearly any membrane with suitable tensile and elongation properties can be used with the vessel of the present invention, including direct seals with regenerated cellulose, a material that is nearly impossible to thermally bond by itself. In yet a further advantage, the present invention also allows rapid assembly of a filter device without requiring the separate bonding of membrane to filter for each cell in the array. This can facilitate manufacturing and reduce costs. All of these advantages are the result of the skin-to-skin crush seal in the ultrafiltration membrane, an element of the claims not found the prior art.

The Bowers reference generally relates to an ultrafiltration vessel, but fails to teach or disclose the required skin-to-skin crush seal. The Examiner suggests that the closest embodiment of Bowers is that illustrated in FIG. 10 A-D and discussed at column 3, lines 5-16. In this embodiment, an array of filter vessels is created by welding or otherwise bonding a sheet or individual wedges of membrane 10 to two molded halves (See FIG. 10 A-C). Bowers then requires treating or cutting away excess membrane at "e" (FIG. 10C) between the tubes if needed to assure dependable joining or sealing, and welding together the halves to form an integral strip in which each well half has two vertical sealed edges at 54 formed at or just next to the center plane.

As stated in the above description, excess membrane is *treated or cut away* to assist with bonding and the halves are *welded* (Col. 8, lines 1-8). A description found on Col. 3, lines 5-16 is cited by the Examiner and further elaborates on the welding step, "A second symmetrically shaped filter-bearing polymer sheet is then laid on top to complete each of the vessel chambers, and the two polymer sheets are bonded together, for example by heat fusion, solvent or ultrasonic welding, or the like to form a strip of n vessels." Not only does Bowers fail to disclose a skin-to-skin crush seal, but the reference actually teaches away from its use. The cutting or treatment at point "e" is a preparation step for the heat fusion, solvent welding, or ultrasonic welding taught in Bowers. In the present invention, the point "e" is where the skin-to-skin crush seal would be formed, and cutting away membrane at this point would be unnecessary and even counterproductive. Bowers therefore fails to disclose the required skin-to-skin crush seal and cannot anticipate claims 7 and 9-12.

In addition, Bowers contains no basis for an obviousness type rejection; there is no suggestion of a skin-to-skin crush seal and the disclosure teaches away from its use. The other references cited in the pending Office Action also fail to remedy the deficiencies of Bowers, because, as explained below, neither Manns nor Landgrebe et al. disclose or suggest the required skin-to-skin crush seal.

35 U.S.C. § 103(a) Claim Rejection

Rejection in view of Manns

The Examiner rejects claim 8 pursuant to 35 U.S.C. § 103(a) as unpatentable over Bowers in view of U.S. Patent 4,948,442 to Manns. In particular, the Examiner argues that claim 8 requires a skin-to-skin crush seal not found in Bowers, but that such a seal is taught by Manns. Applicants respectfully disagree.

Manns fails to teach or disclose any skin-to-skin crush seal, especially the required seal in an ultrafiltration membrane. Instead, Manns generally relates to a micro-titre plate having a filter sheet bound between a culture tray and a harvester tray (FIGS. 1, 5 and 6, Col. 3, lines 20-25, Col. 4, lines 26-34). The culture tray 20 and harvester tray 24 are composed of rigid, water-insoluble, fluid impervious, thermoplastic material and include a channel 38 in the culture tray 20 and a ridge 44 in the harvester tray 24. To manufacture the micro-titre plate of Manns, a filter sheet 22 is placed between the trays, and the ridge 44 on harvester tray 24 is aligned with the channel 38 of culture tray 20 (all shown in FIG. 6). Pressure is then applied between the trays forcing the ridges and channels into close contact and crushing the filter sheet 22. The tips of the ridges and the surfaces of the channels are then *thermally bonded to one another*, preferably by ultrasonic bonding.

Manns therefore discloses thermally bonded trays, not a skin-to-skin crush bond. The ultrasonic bonding step fuses the ridges and channels into a single piece by the application of energy. Although the Examiner seems to focus on the crushing step found in Manns, this step is used to bring the ridge and the channel into close contact so they can be fused. Also, Manns only discloses the use of one filter sheet laid flat between two hard plastic trays. This differs

from a skin-to-skin crush seal that is created by applying pressure between two layers (e.g., ultrafiltration membranes) to create compression.

In addition, Manns creates a bond between two trays instead of creating a skin-to-skin crush seal in a *membrane*. As stated in Mann's disclosure, the resulting thermal bond creates a fluid impervious wall around the well and positively seals each well from its neighboring well. The thermal bond extends the impervious thermoplastic trays across the filter material in the thermal bonding step (See FIG. 7), rather than creating a seal in a membrane. In other words, it appears that the seal in Manns is created by the trays, not the membrane.

The present invention includes a skin-to-skin crush seal that allows the ultrafiltration membrane to cover the full area of the vessel wall, a concept which Manns fails to disclose. Therefore, even if a person of ordinary skill in the art found motivation to combine the teachings of Bowers with the teachings of Manns, the combined disclosure could not result in the present invention.

Rejection in view of Landgrebe et al.

The Examiner rejects claim 6 pursuant to 35 U.S.C. § 103(a) as unpatentable over Bowers in view of U.S. Patent 6,420,455 to Landgrebe et al. ("Landgrebe"). In particular, the Examiner states that the requirement of regenerated cellulose for the interior wall is not found in Bowers, but alleges that this deficiency is taught by Landgrebe. In particular, the Examiner states that Landgrebe uses regenerated cellulose for making molded vessels and cites the following passages, Fig. 1, col. 4 lines 43-51, and col. 10 lines 54-61. Applicants respectfully disagree.

Landgrebe generally relates to antimicrobial compositions containing polymers mixed with one or more photosensitizers. The composition results in a hardened polymer that can be used to construct articles such as a contact lens case (FIG. 1) and a stethoscope (FIG. 2). Nowhere does Landgrebe suggest using the antimicrobial composition to create an ultrafiltration vessel, and in particular an ultrafiltration vessel with an interior wall having a regenerated cellulosic surface as required by claim 6.

Landgrebe lacks any motivation to combine its teachings with those of Bowers. Some suggestion must be provided by the prior art that the antimicrobial polymer composition of Landgrebe could be substituted for the materials used to construct the filter vessel in Bowers. The list of possible uses for the polymer composition in Landgrebe includes articles that benefit from the reduction of microbes, medical devices (e.g., a surgical drape), commonly handled equipment (e.g., keyboard, light switch), and outdoor equipment. Nowhere is there a suggestion that the antimicrobial effect could benefit ultrafiltration. In fact, a person of ordinary skill in the art might find Landgrebe teaches away from the use of its composition in an ultrafiltration vessel because Landgrebe focuses solely on antimicrobial materials and the antimicrobial properties of those materials could damage filtrate.

More importantly, even if the required motivation existed for combining Bowers and Landgrebe, the combined teachings do not contain the limitations of claim 6. Landgrebe lists "regenerated cellulose, for example viscose rayon." The viscose process generally involves treating cellulose with carbon disulfide in sodium hydroxide to form a colloidal dispersion of cellulose xanthate (dithiocarboxylic cellulose ester), and then extrusion into an acid bath to de-esterify and regenerate the cellulose. In the process, cellulose is degraded to smaller chains by the alkali treatment. Morrison and Boyd, Organic Chemistry, p. 798-9, Allyn and Bacon, Boston, 1959. The viscose process and articles made of it as mentioned by Landgrebe, are not suited to molding the high strength clamshell elements needed in the instant invention. In addition, claim 6 requires *surface* regeneration of the vessel surface. Applicants have found a novel way of creating a regenerated vessel *surface* that has the desired properties (e.g., acetone resistance) by briefly dipping cellulose acetate to modify the surface. For instance, in example II surface regeneration provided a modified cellulose acetate part with resistance to acetone for 25 minutes, yet the part was able to apply 8894 psi of crush. By contrast, the fully regenerated part had become rubbery and could not be used for a crush seal. Therefore, Landgrebe not only fails to provide the necessary motivation to combine, but even when combined, the regenerated cellulosic surface and other elements of claim 6 are not disclosed.

Conclusion

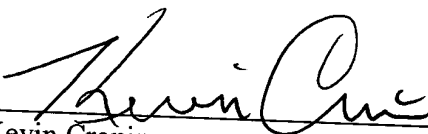
Applicants therefore believe that claims 6, 7 and 8 are patentably distinct from the prior art, and dependent claims 9-12 are allowable at least because they depend from allowable base claims. Allowance is therefore respectfully requested.

The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite allowance of this application.

Respectfully submitted,

Date:

9/12/03



Kevin Cronin

Reg. No. 47,203

Attorney for Applicant(s)

World Trade Center West

155 Seaport Boulevard

Boston, MA 02210-2699

Tel.: (617) 439-2766

Fax: (617) 310-9766

1254113.1